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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,378	08/19/2003	Steven A. Nichtberger	21223	3610

7590

06/29/2004

Mollie M. Yang
Merck & Co., Inc.
Patent Dep., RY60-30
P.O. Box 2000
Rahway, NJ 07056-0907

EXAMINER

SPIVACK, PHYLLIS G

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/643,378	Applicant(s) NICHTBERGER, STEVEN A.	
	Examiner Phyllis G. Spivack	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

A Preliminary Amendment filed August 19, 2003 is acknowledged in which reference to a related earlier application is established.

Claims 1-9 are presented and represent all of the claims under consideration.

The undersigned Examiner supports the goal of the Office to advance prosecution as expediently as is reasonably possible. Cooperation is requested with respect to the timely submission of any references deemed pertinent to the present application along with Form PTO-1449.

A list of co-pending and related cases is requested when Applicant responds to this Office Action.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maynard et al., The Annals of Pharmacotherapy.

Maynard teaches the administration of leukotriene receptor antagonists, such as montelukast and zafirlukast, to treat allergic rhinitis. See column 1, lines 11-14, page 1275, where the decongestant pseudoephedrine is stated to be effective for the symptomatic relief of allergic rhinitis. Combination therapy is suggested. The claims differ in that a pharmaceutical composition comprising both active drug entities is not disclosed. However, one skilled in the allergy art would have been motivated to prepare a pharmaceutical composition comprising both a leukotriene receptor antagonist and

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pseudoephedrine to treat allergic rhinitis and asthma in view of Maynard's teaching. Such would have been obvious in the absence of evidence to the contrary because asthma and allergic rhinitis often occur together and both agents are well established in the prior art as safe and effective. It is generally prima facie obvious to use in combination two or more ingredients that have previously been used separately for the same purpose. In re Kerkhoven, 205 USPQ 1069.

Obviousness does not require absolute predictability but only the reasonable expectation of success. Specific statements in the reference that would spell out the claimed invention are not necessary to show obviousness since questions of obviousness involve not only what references expressly teach, but also what they would collectively suggest to one of ordinary skill in the art. Both pseudoephedrine and various leukotriene inhibitors that are leukotriene receptor antagonists, as montelukast and zafirlukast, are available as orally administrable commercial products in the dosage ranges required by instant claims 7 and 8.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis G.

Spivack at telephone number 571-272-0585.



Phyllis G. Spivack
Primary Examiner
Art Unit 1614

June 25, 2004

PHYLLIS SPIVACK
PRIMARY EXAMINER